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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,956	06/27/2001	William Michael Lafferty	DIVER1280-14	7268
7590 11/17/2004			EXAMINER	
Lisa A. Haile, J.D., Ph.D. Gray Cary Ware & Freidenrich LLP 4365 Executive Drive, Suite 1100 San Diego, CA 92121-2133			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/894,956	LAFFERTY, WILLIAM MICHAEL	
	<b>Examiner</b>	<b>Art Unit</b>	
	BJ Forman	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 August 2004 has been entered.

#### ***Status of the Claims***

2. This action is in response to After-Final papers filed 23 January 2004 in which the specification and claim 1 was amended and further in response to RCE papers filed 12 August 2004 in which claim 1 was amended and the previous rejections were traversed. The amendments have been thoroughly reviewed and entered. The previous objections and rejections in the Office Action dated 20 October 2003, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection are discussed.

Claims 1-10 and 44 are under prosecution.

#### ***Priority***

*Reiterated from the previous office action*

3. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, parent applications 09/636,778 filed 11 August 2000; 09/098,206 filed 16 June 1998; and

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08/876,276 16 June 1997 upon which priority is claimed do not provide adequate support under 35 U.S.C. 112 for claims 1-10 of this application. Specifically, the parent applications do not provide support for the instantly claimed screening apparatus comprising: plurality of capillaries held together in an array, interstitial material disposed between adjacent capillaries; and one or more reference indicia formed within the interstitial material. Therefore, the effective filing date for instant Claim 1-10 is the filing date of parent application 09/444,112 i.e. 22 November 1999.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-10 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation “permanently bound” is added to the newly amended independent claim 1 from which claims 2-10 and 44 depend. However, the specification fails to define or provide any disclosure to support such claim recitation.

Applicant cites the passage at page 5, ¶ 29 for support of the newly claimed “permanently bound”. While the cited passage teaches various species of capillary binding, the specification does not teach or define the newly claimed genus of permanent binding.

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Furthermore, the passage does not teach or describe which of the binding techniques listed provide the claimed permanent binding.

Therefore, the newly claimed "permanently bound" was not described in the specification in such a way as to reasonably convey to one skilled in the art that applicant, at the time the claimed invention was made, had possession of the newly claimed invention.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Borrelli et al (U.S. Patent No. 6,350,618, filed 27 April 1999).

Regarding Claim 1, Borrelli et al disclose a sample screening apparatus comprising: a plurality of capillaries permanently bound in a non-uniform array (Fig. 2, Column 9, lines 18-34) wherein each capillary comprises at least one wall defining a lumen for retaining a sample by capillary forces (Column 10, lines 47-50); and interstitial material disposed between adjacent capillaries (e.g. sintered particles wherein following the sintering process a "honeycomb block" of channels is obtained, Column 4, line 55-Column 5, line 5).

Regarding Claim 6, Borrelli et al disclose the array wherein the lumen of each capillary has an internal diameter of between  $3\mu\text{m}$  and  $500\mu\text{m}$  (Column 9, lines 33-34).

Regarding Claim 7, Borrelli et al disclose the array wherein the plurality of capillaries are held together by being fused to one another (i.e. via sintering, Column 4, line 55-Column 5, line 5).

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (U.S. Patent No. 5,763,263 issued 9 June 1998) in view of Borrelli et al (U.S. Patent No. 6,350,618, filed 27 April 1999).

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Regarding Claim 1, Dehlinger discloses a sample screening apparatus comprising: a plurality of capillaries permanently bound together in an array wherein each capillary comprises at least one wall defining a lumen for retaining a sample; and interstitial material disposed between adjacent capillaries (Column 7, line 50-Column 8, line 33). Dehlinger specifically teaches the capillaries are arranged in a "close-packed array" (Column 8, line 17-20) but is silent regarding array uniformity. However, non-uniform arrangement of capillaries was well known in the art as taught by Borrelli et al. The arrangement illustrated by Borrelli et al provides the capillaries as closely packed as possible (i.e. with a minimum of spacing Fig. 2). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the non-uniform capillary arrangement of Borrelli et al to the capillary array of Dehlinger to thereby provide the most closely packed array they desire (Column 8, lines 17-20).

Regarding Claim 2, Dehlinger discloses the array wherein each capillary has an aspect ration of between 10:1 and 100:1 (i.e. 20-200 $\mu$  inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 3, Dehlinger discloses the array wherein each capillary has an aspect ration of between 20:1 and 100:1 (i.e. 20-200 $\mu$  inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 4, Dehlinger discloses the array wherein each capillary has an aspect ration of between 40:1 and 50:1 (i.e. 20-200 $\mu$  inner diameter and length of 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 5, Dehlinger discloses the array wherein each capillary has a length of between 5m m and 10 cm (i.e. 0.5 to 3 cm, Column 8, lines 3-16).

Regarding Claim 6, Dehlinger discloses the array wherein the lumen of each capillary has an internal diameter of between 3 $\mu$  m and 500 $\mu$  m (i.e. 20-200 $\mu$  inner diameter, Column 8, lines 3-16).

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Regarding Claim 7, Dehlinger discloses the array wherein the plurality of capillaries are fused together to form the array (i.e. bonded or fixed, Column 8, lines 17-27).

**Response to Applicant's comments**

10. Applicant asserts that Dehlinger is silent regarding a non-uniform array, but in contrast provides a position-addressable array for library construction. Applicant further asserts that the method of Dehlinger "dictates that capillaries be in a uniform arrangement". The arguments have been considered but are not found persuasive because, as stated above, Dehlinger specifically teaches the preferred "closely packed" capillary arrangement (Column 8, lines 17-20). While they do not illustrate capillary arrangement, Borrelli et al do illustrate capillary arrangement wherein the capillaries are most closely packed. Therefore, one of ordinary skill would have been motivated to provide the arrangement taught by Borrelli et al based on the preferred "closely packed" teaching of Dehlinger. Furthermore, Applicant's assertion that the method of Dehlinger dictates uniform arrangement is not supported by factual evidence of such.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. (see (MPEP 716.01(c)).

Applicant asserts other uses for the claimed capillaries, not provided by Dehlinger e.g. liquids can be separated by a bubble of air, capillaries open at both ends permits reactants to be imbibed into the tubes without pumping. The arguments have been considered but are not found persuasive because these limitations are not elements of the claimed apparatus. Therefore, the arguments are not commensurate in scope with the claims.



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Applicant further argues that the reactants of Dehlinger are linked to the internal wall of the capillaries while the instant claims require retaining the sample by capillary forces. The argument has been considered but is not found persuasive because the open claim language "comprising" encompasses any additional elements of Dehlinger e.g. reactants on the internal walls. Furthermore, the Claims merely define the capillaries as comprising at least one wall defining a lumen. The claim recites an intended use for the capillary wall i.e. retaining a sample by capillary forces. However, the intended use does not define any structural element that defines the capillaries over those of Dehlinger. While the intended use does not define the capillary, it is noted that Dehlinger specifically teaches use of capillary forces for retaining the sample "unplugged tubes in the cassette, such as tubes 71, 73, then imbibe the reagent solution by capillary filling of these tubes as shown" (Column 10, lines 63-67 and Fig. 4c).

11. Claims 8-10 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (U.S. Patent No. 5,763,263 issued 9 June 1998) ) in view of Borrelli et al (U.S. Patent No. 6,350,618, filed 27 April 1999) as applied to Claim 1 above and further in view of Winkler et al (U.S. Patent No. 5,677,195).

Regarding Claim 44, Dehlinger teaches the sample screening apparatus comprising: a plurality of capillaries held together in an array wherein each capillary comprises at least one wall defining a lumen for retaining a sample; and interstitial material disposed between adjacent capillaries (Column 7, line 50-Column 8, line 33) but they do not teach the apparatus further comprises one or more reference indicia disposed within the interstitial material.

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However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al who specifically teach that reference indicia are essential for consistent and precise positionally addressable array construction and use (Column 18, line 51-Column 19, line 24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the reference indicia of Winkler et al in the capillary array of Dehlinger thereby placing reference indicia within the interstitial material of the array for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claims 8 and 9, Dehlinger teaches their array of subarrays provides a positionally addressable device (Column 4, line 65-column 5, line 4) but they do not teach the interstitial material comprises one or more reference indicia formed at intervals (Claim 8) and formed at edges (Claim 9). However, reference indicia within interstitial material of an array was well known in the art at the time the claimed invention was made as taught by Winkler et al (Column 18, line 51-Column 19, line 24). And Winkler et al specifically teach arrays comprising reference indicia at formed at array intervals (i.e. local) and at edges (i.e. global) wherein the local and/or global indicia are essential for exact positioning and detecting of array addresses (Column 19, lines 4-39). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the local and/or global reference indicia of Winkler et al in the positionally addressable array of Dehlinger and to place the reference indicia at intervals and/or at edges of the array for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

Regarding Claim 10, Dehlinger teaches the array wherein capillary array comprises glass (Column 7, lines 40-47; Column 8, lines 34-44; and Column 13, line 56-Column 14, line 32) but they do not teach the array comprises reference indicia formed of glass. Winkler et al

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teach a similar array wherein the array comprises glass (Column 6, lines 49-60 and Column 14, lines 45-55) and they teach the array comprises reference indicia (Column 19, lines 4-24). Therefore, the reference indicia of Winkler are formed of glass as claimed. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the glass array of Dehlinger by forming reference indicia on the array as taught by Winkler et al for the expected benefits of consistent and precise array construction and use as taught by Winkler et al (Column 18, line 51-Column 19, line 24).

#### **Response to Applicant's comments**

12. Applicant reiterates the arguments discussed above regarding Dehlinger's position addressable arrays and the instantly claimed non-uniform capillary arrangement. The arguments have been considered as addressed above.

#### ***Double Patenting***

13. The previous rejections under statutory type double patenting is withdrawn in view of the fact that the conflicting application has been abandoned.

#### **Conclusion**

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

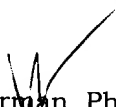
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
November 16, 2004